



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

re Application of : Maria KORDOWICZ et al.
Serial No.: 10/009,500

Filed: December 11, 2001

Group Art Unit: 1632

Examiner: Unassigned

For: HYALURONIDASE FROM THE HIRUDINARIA MANILLENSIS, ISOLATION,
PURIFICATION AND RECOMBINANT METHOD OF PRODUCTION

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §§ 1.56, 1.97 and 1.98

Assistant Commissioner for Patents
Washington, D. C. 20231

Sir:

This information disclosure statement is made in accordance with 37 C.F.R. §§ 1.600, 1.2900
and 1.98 as follows:

Timing and Fees

- Under 37 C.F.R. § 1.97(b), no fee or statement is required for filing this information disclosure statement is filed:
- within three months after the filing date of a national application other than a CPA under § 1.53(d);
- within three months after the actual filing date of the national phase of a PCT application; OR
- before the mailing of a first substantive office action (including after filing of an RCE).
- Under 37 C.F.R. § 1.97(c), this information disclosure statement is filed after the periods specified in 37 C.F.R. § 1.97(b), but before the mailing date of:
- a final rejection under 37 C.F.R. 1.113;
- termination of prosecution, e.g. Ex Parte Quayle, M.P.E.P. § 609(B)(2); OR
- a notice of allowance under 37 C.F.R. § 1.311; and

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1.600, 1.2900

is accompanied by:

- the statement as specified in 37 C.F.R. § 1.97(e) set out below; OR
 - a check covering the fee of \$180.00 under 37 C.F.R. § 1.17(p).
- Under 37 C.F.R. § 1.97(d), this information disclosure statement is filed after the mailing date of the following actions which have not been withdrawn:
- a final action under 37 C.F.R. § 1.113;
 - termination of prosecution, e.g. Ex Parte Quayle, M.P.E.P. § 609(B)(2); OR
 - a notice of allowance under 37 C.F.R. § 1.311;

AND is filed on or before payment of the issue fee; AND is accompanied by:

- the statement as specified in 37 C.F.R. § 1.97(e) as set forth below, and the fee of \$180.00 under 37 C.F.R. § 1.17(p).

Statements Under 37 C.F.R. 1.97(e)

- Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application having a mailing date not more than three months prior to the filing date of this information disclosure statement; or
- No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the undersigned attorney after making reasonable inquiry, no item of information contained in this information disclosure statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing date of the information disclosure statement.

Cited Materials

- Copies of materials listed but not attached were cited in benefit (35 U.S.C. § 120) ancestor application Serial No. _____, on Form 892 by the Examiner and/or Form 1449 by the applicant; see 37 C.F.R. § 1.98(d).
- Copies of materials listed but not attached were cited in an international search report dated November 15, 2000.
- Copies of the materials listed are attached (except for the foregoing).

Non-English Language References

- The reference(s): _____ in the English-language is (are) indicated by commercial data bases to correspond to the non-English reference(s): _____, respectively.
- (An) English-language translation(s) of the references: _____ is (are) provided.
- A commercial English-language abstract of reference(s) _____ is (are) provided.
- An English-language search report or equivalent paper from a foreign patent office is provided indicating the relevance of the cited reference(s).
- A foreign-language search report from a foreign patent office is provided, and pertinent parts are translated substantively below:

X = document of particular relevance when it is taken alone
Y = document of particular relevance when it is combined with another such document
A = document defining the general state of the art
O = non-written disclosure
P = intercalated document
T = document cited to understand the theory or principle underlying the invention
E = patent document which has the benefit of a date earlier than the filing date and which was published only on or after this filing date
D = cited in the application
L = cited for another reason
& = publication of member of same patent family

- Translation of other relevant information on foreign search report

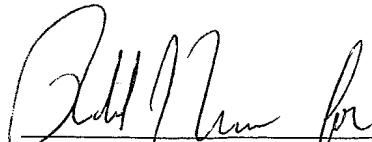
Other Information

Payment of Fees Due (If Any):

- A check for \$ _____ covering the fee identified above is attached.
- Please charge to Deposit Account No. 13-3402 \$ _____ for the fee identified above.

The Commissioner is hereby authorized to charge or credit any overpayment to Deposit Account #13-3402, two copies of this paper are attached for this purpose.

Respectfully submitted,



305a5

Anthony J. Zelano, Reg. No. 27,969
Attorney/Agent for Applicants

MILLEN, WHITE, ZELANO
& BRANIGAN, P.C.
Arlington Courthouse Plaza 1
2200 Clarendon Blvd. Suite 1400
Arlington, Virginia 22201
Telephone: (703) 243-6333
Facsimile: (703) 243-6410

Attorney Docket No.: MERCK-2332

Date: April 21, 2003

AJZ:jr

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U.S. PATENT & TRADEMARK OFFICE
Substitute for form 1449A/PTO

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U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet

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of

2

Complete if Known

| | |
|------------------------|------------------------|
| Application Number | 10/009.500 |
| Filing Date | December 11, 2001 |
| First Named Inventor | Maria KORDOWICZ et al. |
| Group Art Unit | 1632 |
| Examiner Name | Unassigned |
| Attorney Docket Number | MERCK-2332 |

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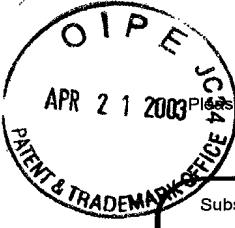
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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 2 of 2

| <i>Complete if Known</i> | |
|--------------------------|------------------------|
| Application Number | 10/009,500 |
| Filing Date | December 11, 2001 |
| First Named Inventor | Maria KORDOWICZ et al. |
| Group Art Unit | 1632 |
| Examiner Name | Unassigned |
| Attorney Docket Number | MERCK-2332 |

NON PATENT LITERATURE DOCUMENTS

| | | | |
|-----------------------|--|--------------------|--|
| Examiner Signature | | Date Considered | |
|-----------------------|--|--------------------|--|

¹EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

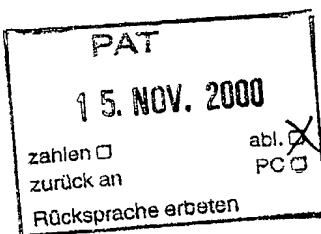
Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To:

MERCK PATENT GMBH
D-64271 Darmstadt
GERMANY



PCT

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT
OR THE DECLARATION

(PCT Rule 44.1)

| | | | |
|--|--|---|--|
| Applicant's or agent's file reference 0099216-BZmi | | Date of mailing <i>(day/month/year)</i> 15/11/2000 | |
| International application No. PCT/EP 00/ 05181 | | FOR FURTHER ACTION See paragraphs 1 and 4 below International filing date <i>(day/month/year)</i> 06/06/2000 | |
| Applicant MERCK PATENT GMBH | | | |

1. The applicant is hereby notified that the International Search Report has been established and is transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the International Search Report; however, for more details, see the notes on the accompanying sheet.

Where? Directly to the International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland
Fascimile No.: (41-22) 740.14.35

For more detailed instructions, see the notes on the accompanying sheet.

2. The applicant is hereby notified that no International Search Report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.

3. With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

- the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
- no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. Further action(s): The applicant is reminded of the following:

Shortly after 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

Within 19 months from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later).

Within 20 months from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.

Name and mailing address of the International Searching Authority

 European Patent Office, P.B. 5818 Patentlaan 2
 NL-2280 HV Rijswijk
 Tel. (+31-70) 340-2040, Tx. 31 651 epo nl.
 Fax: (+31-70) 340-3016

Authorized officer

Andria Overbeeke-Siepkens

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the PCT Applicant's Guide, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only.

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

| | | |
|--|---|---|
| Applicant's or agent's file reference 0099216-Bzmi | FOR FURTHER ACTION | see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below. |
| International application No. PCT/EP 00/ 05181 | International filing date (day/month/year) 06/06/2000 | (Earliest) Priority Date (day/month/year) 12/06/1999 |
| Applicant MERCK PATENT GMBH | | |

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 3 sheets.

It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

- a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).
- b. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international search was carried out on the basis of the sequence listing :
 - contained in the international application in written form.
 - filed together with the international application in computer readable form.
 - furnished subsequently to this Authority in written form.
 - furnished subsequently to this Authority in computer readable form.
 - the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
 - the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. Certain claims were found unsearchable (See Box I).

3. Unity-of Invention Is lacking (see Box II).

4. With regard to the title,

- the text is approved as submitted by the applicant.
- the text has been established by this Authority to read as follows:

5. With regard to the abstract,

- the text is approved as submitted by the applicant.
- the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the drawings to be published with the abstract is Figure No.

- as suggested by the applicant.
- because the applicant failed to suggest a figure.
- because this figure better characterizes the invention.

None of the figures.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/EP 00/05181

Box III TEXT OF THE ABSTRACT (Continuation of item 5 of the first sheet)

Line 02 in the text, please remove the word "novel".

Line 03 in the text, please remove the word "new".

INTERNATIONAL SEARCH REPORT

International Application No

PCT/EP 00/05181

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 C12N15/52 C12N9/26 A61K38/43

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 C12N A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

BIOSIS, EMBASE, CHEM ABS Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category ° | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|------------|---|--------------------------------|
| X | EP 0 193 330 A (BIOPHARM LTD) 3 September 1986 (1986-09-03) cited in the application the whole document ---- | 1-4, 6, 8, 9, 16, 17, 20 |
| A | JONES C. P. AND SAWYER R. T.: "Heparin inhibits mammalian, but not leech hyaluronidase." THROMBIN RESEARCH, vol. 55, no. 6, 1989, pages 791-796, XP000953413 the whole document ---- | 1-20 |
| A | US 5 827 721 A (FORMBY BENT ET AL) 27 October 1998 (1998-10-27) column 6, line 24 - line 61; example 1 ----- | 7 |



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

° Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

Date of mailing of the international search report

1 November 2000

15/11/2000

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl.
Fax: (+31-70) 340-3016

Authorized officer

Mandl, B

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/EP 00/05181

| Patent document cited in search report | Publication date | Patent family member(s) | | Publication date |
|--|------------------|-------------------------|-----------|------------------|
| EP 0193330 A | 03-09-1986 | DE | 3688710 A | 26-08-1993 |
| | | DE | 3688710 T | 18-11-1993 |
| | | US | 4820516 A | 11-04-1989 |
| US 5827721 A | 27-10-1998 | US | 5747027 A | 05-05-1998 |
| | | WO | 9631596 A | 10-10-1996 |